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(54) **RETRIEVAL WIRE CENTERING DEVICE**

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Description

Technical Field

[0001] The disclosure relates generally to percutaneous medical devices and more particularly to percutaneous medical devices for implantation into the left atrial appendage (LAA) of a heart.

Background

[0002] Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting over 5.5 million people worldwide. Atrial fibrillation is the irregular, chaotic beating of the upper chambers of the heart. Electrical impulses discharge so rapidly that the atrial muscle quivers, or fibrillates. Episodes of atrial fibrillation may last a few minutes or several days. The most serious consequence of atrial fibrillation is ischemic stroke. It has been estimated that up to 20% of all strokes are related to atrial fibrillation. Most atrial fibrillation patients, regardless of the severity of their symptoms or frequency of episodes, require treatment to reduce the risk of stroke. The left atrial appendage (LAA) is a small organ attached to the left atrium of the heart as a pouch-like extension. In patients suffering from atrial fibrillation, the left atrial appendage may not properly contract with the left atrium, causing stagnant blood to pool within its interior, which can lead to the undesirable formation of thrombi within the left atrial appendage. Thrombi forming in the left atrial appendage may break loose from this area and enter the blood stream. Thrombi that migrate through the blood vessels may eventually plug a smaller vessel downstream and thereby contribute to stroke or heart attack. Clinical studies have shown that the majority of blood clots in patients with atrial fibrillation are found in the left atrial appendage. As a treatment, medical devices have been developed which are positioned in the left atrial appendage and deployed to close off the ostium of the left atrial appendage. Over time, the exposed surface(s) spanning the ostium of the left atrial appendage becomes covered with tissue (a process called endothelialization), effectively removing the left atrial appendage from the circulatory system and reducing or eliminating the amount of thrombi which may enter the blood stream from the left atrial appendage.

[0003] A continuing need exists for improved medical devices and methods to control thrombus formation within the left atrial appendage of patients suffering from atrial fibrillation.

[0004] US 2009/0062841 A1 is related to a multi-layer occluder for treating a target site within the body. The occluder includes first and second layers. The first layer includes braided strands of metallic material, and the second layer includes braided strands of polymeric material. At least one of the first or second layers is configured to facilitate thrombosis.

[0005] WO 2014/011865 A1, which is a prior art doc-

ument in the meaning of Article 54(3) EPC, is related to an occlusion device for an atrial appendage. The device comprises a cage-like structure formed of struts. The struts have proximal strut ends and distal strut ends, wherein at the proximal end of the device the struts extend towards the central axis and are connected to each other at their proximal strut ends. The proximal strut ends are connected at a proximal collar, which is provided with an insert for attaching the device to a tether wire. At least some of the struts are connected to each other at their distal strut ends within the cage-like structure so that the struts form an atraumatic distal end of the device. The device further includes a filter membrane supported on the outer surface of the cage-like structure.

[0006] WO 2003/0181942 A1 is a further publication related to an occlusion device for an atrial appendage.

Summary

[0007] The invention is defined in claim 1, with further embodiments defined in the dependent claims.

[0008] A medical implant includes a frame configured to actuate between a collapsed configuration and an expanded configuration, and an occlusive element covering at least a portion of the frame, wherein a proximal end of the frame forms a generally tubular portion, the tubular portion being configured to attach to a distal end of a core wire, and wherein the tubular portion of the frame includes a threaded insert coupled thereto.

[0009] An occlusive implant system includes a catheter having a lumen extending therethrough, a core wire slidably and rotatably disposed within the lumen, the core wire having a threaded member disposed at a distal end thereof, and a medical implant having an expandable frame, an occlusive element disposed on the frame, and a threaded insert coupled to a proximal portion of the frame, wherein the threaded member is removably coupled to the threaded insert.

[0010] A method of making a centering core wire may include obtaining an elongate core wire having a threaded member disposed at a distal end thereof; obtaining a guide element having an aperture or lumen disposed therein; inserting a proximal end of the elongate core wire into the aperture or lumen; sliding the guide element distally over the elongate core wire into contact with the threaded member; and applying a polymeric jacket over the elongate core wire from the proximal end to the guide element; wherein the polymeric jacket retains the guide element against the threaded member.

Brief Description of the Drawings

[0011]

Figure 1 is a side view of an example medical implant and delivery assembly;

Figure 2 is a partial cross-sectional view of an example medical implant disposed within a delivery as-

sembly;

Figure 3 is a perspective view of an example medical implant;

Figure 3A is a partial cross-sectional view of the example medical implant of Figure 3;

Figure 4 is a perspective view of an example medical implant;

Figure 4A is a partial cross-sectional view of the example medical implant of Figure 4;

Figures 5A and 5B illustrate the extent of relative movement between certain elements of the delivery assembly of Figure 1;

Figure 6 is a partial cross-sectional view of an example medical implant being retracted into a delivery catheter;

Figure 7 is a side view of an example guide element;

Figure 8 is a side view of an example guide element;

Figure 9 is a side view of an example guide element;

Figure 10 is a side view of an example medical implant connected to an example core wire having the example guide element of Figure 7;

Figure 10A is a side view of the example medical implant of Figure 10 misaligned with an example delivery catheter lumen; and

Figure 11 is a side view of the example medical implant of Figure 10 being centered with an example delivery catheter lumen.

[0012] While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in greater detail below. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. The invention is defined by the claims.

Detailed Description

[0013] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0014] The terms "upstream" and "downstream" refer to a position or location relative to the direction of blood flow through a particular element or location, such as a vessel (i.e., the aorta), a heart valve (i.e., the aortic valve), and the like.

[0015] The terms "proximal" and "distal" shall generally refer to the relative position, orientation, or direction of an element or action, from the perspective of a clinician using the medical device, relative to one another. While the terms are not meant to be limiting, "proximal" may generally be considered closer to the clinician or an exterior of a patient, and "distal" may generally be considered to be farther away from the clinician, along the length of the medical device.

[0016] The terms "monolithic" and "unitary" shall generally refer to an element or elements made from or consisting of a single structure or base unit/element. A mon-

olithic and/or unitary element shall exclude structure and/or features made by assembling or otherwise joining multiple discrete elements together.

[0017] All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about", in the context of numeric values, generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the term "about" may include numbers that are rounded to the nearest significant figure. Other uses of the term "about" (i.e., in a context other than numeric values) may be assumed to have their ordinary and customary definition(s), as understood from and consistent with the context of the specification, unless otherwise specified.

[0018] Weight percent, percent by weight, wt%, wt-%, % by weight, and the like are synonyms that refer to the concentration of a substance as the weight of that substance divided by the weight of the composition and multiplied by 100.

[0019] The recitation of numerical ranges by endpoints includes all numbers within that range, including the endpoints (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0020] The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings are intended to illustrate but not limit the claimed invention. Those skilled in the art will recognize that the various elements described and/or shown may be arranged in various combinations and configurations. The various individual elements described below, even if not explicitly shown in a particular combination, are nevertheless contemplated as being combinable or arrangable with each other to form other additional embodiments or to complement and/or enrich the described embodiment(s), as would be understood by one of ordinary skill in the art.

[0021] The occurrence of thrombi in the left atrial appendage (LAA) during atrial fibrillation may be due to stagnancy of the blood pool in the LAA. The blood may still be pulled out of the left atrium by the left ventricle, however less effectively due to the irregular contraction of the left atrium caused by atrial fibrillation. Therefore, instead of an active support of the blood flow by a contracting left atrium and left atrial appendage, filling of the left ventricle may depend primarily or solely on the suction effect created by the left ventricle. Further, the contraction of the left atrial appendage may not be in sync with the cycle of the left ventricle. For example, contraction of the left atrial appendage may be out of phase up to 180 degrees with the left ventricle, which may create significant resistance to the desired flow of blood. Further still, most left atrial appendage geometries are complex and highly variable, with large irregular surface areas and a narrow ostium or opening compared to the depth of the left atrial appendage. These aspects as well as others,

taken individually or in various combinations, may lead to high flow resistance of blood out of the left atrial appendage.

[0022] In an effort to reduce the occurrence of thrombi formation within the left atrial appendage and prevent thrombi from entering the blood stream from within the left atrial appendage, medical devices have been developed that close off the left atrial appendage from the heart and/or circulatory system, thereby lowering the risk of stroke due to thrombolytic material entering the blood stream from the left atrial appendage. Difficulties encountered during placement of said medical device(s) may occasionally require removal and/or recapture procedures. In an effort to ease recapture procedures and/or to provide a medical device suitable for long term implantation, favorable new features have been developed.

[0023] Turning now to the figures, Figure 1 illustrates an example delivery assembly and/or implant system 10 including an example medical implant 20 disposed at a distal end 32 of an example core wire 30. The core wire 30 may be slidably and/or rotatably disposed within a lumen 42 of a delivery catheter 40. In some embodiments, a proximal end 34 of the core wire 30 may extend proximally of a proximal end of the delivery catheter 40 for manual manipulation by a clinician or practitioner. In some embodiments, the example medical implant 20 may be removably attached, joined, or otherwise connected to the distal end 32 of the example core wire 30. An example medical implant 20 may be configured to actuate from a collapsed configuration to an expanded configuration when (or after being) extended distally from the delivery catheter 40, as seen in Figure 1 for example. Figure 2 illustrates the example medical implant 20 disposed within a distal portion of the lumen 42 of the delivery catheter 40 in the collapsed configuration. It is contemplated that any and/or all example medical implants disclosed herein may be used in accordance with and/or be associated with the example delivery assembly and/or implant system 10 described above.

[0024] Figures 3 and 3A illustrate an example medical implant 100 having a frame 110 configured to actuate between a collapsed configuration and an expanded configuration. In some embodiments, the example medical implant 100 may include an occlusive element 120 disposed on, disposed over, disposed about, or covering at least a portion of the frame 110. In some embodiments, the occlusive element 120 may be disposed on, disposed over, disposed about or cover at least a portion of an outer (or outwardly-facing) surface of the frame 110. In some embodiments, a proximal end of the frame 110 may form a generally tubular portion 112, the generally tubular portion 112 being configured to attach to or couple to a distal end of a core wire 30. In some embodiments, the generally tubular portion 112 of the frame 110 may include a threaded insert 130 coupled thereto. In some embodiments, the threaded insert 130 may be at least partially disposed within the generally tubular portion 112 of the frame 110. In some embodiments, the threaded

insert 130 may be configured to and/or adapted to couple with, join to, mate with, or otherwise engage a threaded member 36 disposed at the distal end 32 of the core wire 30.

[0025] In some embodiments, a first portion of the occlusive element 120 may be disposed between the threaded insert 130 and the generally tubular portion 112. In some embodiments, the first portion of the occlusive element 120 may be pinched or held between the threaded insert 130 and the generally tubular portion 112. In some embodiments, the threaded insert 130 may include a curved or angled proximally-facing surface 132 that extends radially outward from threads formed within a center of the threaded insert 130. In some embodiments, the curved or angled proximally-facing surface 132 may extend proximally of the occlusive element 120 in the expanded configuration and/or the collapsed configuration. In some embodiments, the curved or angled proximally-facing surface 132 may have an outer extent that is disposed radially outward from the first portion of the occlusive element 120 and/or the generally tubular portion 112. In some embodiments, the frame 110 may include a plurality of proximally-facing hooks 118 disposed about a periphery of the frame 110 in the expanded configuration. In some embodiments, the plurality of proximally-facing hooks 118 may provide an anchoring mechanism to aid in retaining a deployed medical implant 100 at a target site within a patient's anatomy (i.e., the left atrial appendage, for example).

[0026] Figures 4 and 4A illustrate a medical implant 200 according to the invention, having a frame 210 configured to actuate between a collapsed configuration and an expanded configuration. The medical implant 200 includes an occlusive element 220 covering at least a portion of the frame 210. In some embodiments, the occlusive element 220 may cover at least a portion of an outer (or outwardly-facing) surface of the frame 210. A proximal end of the frame 210 forms a generally tubular portion 212, the generally tubular portion 212 being configured to attach to or couple to a distal end 32 of a core wire 30. The generally tubular portion 212 of the frame 210 includes a threaded insert 230 coupled thereto. The frame 210 includes

an annular collar member 240 at least partially disposed within the generally tubular portion 212 and coupled thereto. The

threaded insert 230 is coupled to the annular collar member 240. The threaded insert 230 is at least partially disposed within the annular collar member 240. A pin element 250 couples the annular collar member 240 to the frame 210. In some embodiments, the pin element 250 may couple the annular collar member 240 and/or the threaded insert 230 to the frame 210 and/or to each other. In some embodiments, the annular collar member 240 and/or threaded insert 230 may be fixedly attached to and/or coupled with the generally tubular portion 212 of the frame 210 and/or each other. In some embodiments, the annular collar member 240 and/or threaded insert

230 may be permanently attached to and/or coupled with the generally tubular portion 212 of the frame 210 and/or each other. In some embodiments, the annular collar member 240 and/or threaded insert 230 may be removably attached to and/or coupled with the generally tubular portion 212 of the frame 210 and/or each other. In some embodiments, the threaded insert 230 may be configured to and/or adapted to reversibly and/or removably couple with, join to, mate with, or otherwise engage a threaded member 36 disposed at the distal end 32 of the core wire 30.

[0027] In some embodiments, a first portion of the occlusive element 220 may be disposed between the threaded insert 230 and the annular collar member 240. In some embodiments, the first portion of the occlusive element 220 may be pinched or held between the threaded insert 230 and the annular collar member 240. In some embodiments, the threaded insert 230 may be disposed distally of a portion of the occlusive element 220 disposed outside of the annular collar member 240 in the expanded configuration and/or the collapsed configuration. In some embodiments, an outer portion of the occlusive element 220 may be defined as that part of the occlusive element 220 disposed outside of the annular collar member 240. In some embodiments, the outer portion of the occlusive element 220 may be disposed radially outward from the threaded insert 230 in the expanded configuration. In some embodiments, the frame 210 may include a plurality of proximally-facing hooks 218 disposed about a periphery of the frame 210 in the expanded configuration. In some embodiments, the plurality of proximally-facing hooks 218 may provide an anchoring mechanism to aid in retaining a deployed medical implant 200 at a target site within a patient's anatomy (i.e., the left atrial appendage, for example).

[0028] In some embodiments, the medical implant 200 of Figure 4 may have a reduced amount of exposed material (i.e., metallic material) at the threaded insert compared to the medical implant 100 of Figure 3. Applicants have found that reducing the amount of metallic material exposed to the bloodstream may provide certain advantages such as reduced thrombus formation and/or more rapid endothelialization.

[0029] As illustrated in Figures 5A and 5B, in some embodiments, a core wire 30 may have a maximum outer diameter that is considerably smaller than a minimum inner diameter of a lumen 42 of a delivery catheter 40. The inner diameter of the lumen 42 of the delivery catheter 40 may be sized to accommodate a medical implant 20 within the lumen 42 in a collapsed configuration. The outer diameter of the core wire 30 may be sized to provide sufficient flexibility to the core wire 30 and the delivery assembly and/or implant system 10 for navigation through a patient's vasculature to a target site (i.e., the left atrial appendage, for example) while maintaining a desired level of torquability and/or pushability.

[0030] As may be seen in Figures 5A and 5B, the difference in size between the core wire 30 and the lumen

42 may allow a significant amount of "play", or lateral movement relative to a central axis of the lumen 42, between the core wire 30 and the delivery catheter 40. As such, a medical implant 20 and/or the distal end 32 of the core wire 30 may become misaligned with the lumen 42 of the delivery catheter 40 after being extended distally from the lumen 42, such as during deployment of the medical implant 20 and/or during removal or recapture of the medical implant 20. During some procedures, it may be necessary to withdraw and/or recapture the medical implant 20 after initial placement, prior to releasing the medical implant 20 from the core wire 30. For example, if an inadequate seal is achieved between the medical implant 20 and the surrounding tissue (i.e., the ostium of the left atrial appendage, for example), a practitioner may recapture the medical implant 20 and deploy it again to ensure proper placement. Alternatively, it may be necessary at some point to remove the medical implant after deployment and release within a patient's anatomy. During recapture procedures, a distal end 44 of the delivery catheter 40 may come into contact with the medical implant 20 and/or the occlusive element disposed thereon, as seen in Figure 6. If the medical implant 20 is not generally centered within the distal opening of the lumen 42, the forces required to actuate the frame from the expanded configuration to the collapsed configuration may be increased, and in some cases high enough to result in tearing of, or damage to, the occlusive element as the occlusive element is pinched between the frame and the delivery catheter 40, thereby requiring full removal from patient and replacement of the implant 20 before the procedure may proceed. Accordingly, a feature which may result in centering of the implant 20 within the lumen 42 may be beneficial in at least some circumstances.

[0031] Figures 7-9 illustrate an example core wire 30 having a threaded member 36 at a distal end 32. In some embodiments, the threaded member 36 may be configured and/or adapted to engage, attach to, connect to, and/or mate with a threaded insert of an example medical implant 20. The example core wire 30 may include a guide element 35 disposed about the core wire 30 adjacent a proximal end of the threaded member 36. The guide element 35 may be shaped and/or configured to center the core wire 30 and/or the medical implant 20 within the lumen 42 of the delivery catheter 40. In some embodiments, the guide element 35 may include a curved, convex proximal surface and a generally flat distal surface, as shown in Figure 7, for example. In some embodiments, the guide element 35 may include a conical proximal surface and a generally flat distal surface, as shown in Figure 8, for example. In some embodiments, the guide element 35 may include a generally rounded, bulbous, convex outer surface, as shown in Figure 9, for example. In some embodiments, a distal surface of the guide element 35 may be configured to and/or adapted to contact or engage the medical implant 20 when the threaded member 36 is engaged with, attached to, connected to, and/or mated with the threaded insert, as seen

for example in Figures 10-11. In some embodiments, a distal surface of the guide element 35 may not contact or engage the medical implant 20 when the threaded member 36 is engaged with, attached to, connected to, and/or mated with the threaded insert, and the distal surface of the guide element 35 may be spaced apart from the medical implant 20.

[0032] In some embodiments, an occlusive implant system 10 may include a delivery catheter 40 having a lumen 42 extending therethrough, a core wire 30 slidably and/or rotatably disposed within the lumen 42, the core wire 30 having a threaded member 36 disposed at a distal end 32 thereof, and a medical implant 20 having an expandable frame, an occlusive element disposed on the frame, and a threaded insert coupled to a proximal portion of the frame, wherein the threaded member 36 may be removably coupled to the threaded insert, as shown for example in Figures 10-11. In the exemplary figures provided herewith, the example core wire 30 is shown attached to the example medical implant 200 described herein. However, the example core wire 30 may also be used with the example medical implant 100 described herein or other similar medical implants/devices. In some embodiments, the frame may be actuatable between a collapsed configuration and an expanded configuration. In some embodiments, the frame may be self-expanding. In some embodiments, the frame may be manually actuatable from the collapsed configuration to the expanded configuration. In some embodiments, a portion of the occlusive element may be disposed between the threaded insert and the proximal portion of the frame. In some embodiments, a portion of the occlusive element may extend proximally of the threaded insert. In some embodiments, the medical implant 20 may include an annular collar member disposed between the proximal portion of the frame and the threaded insert. In some embodiments, the annular collar member and/or the threaded insert may be removably and/or reversibly coupled to, attached to, connected to, and/or engaged with the proximal portion of the frame by a pin element. In some embodiments, the annular collar member and/or the threaded insert may be fixedly and/or permanently coupled to, attached to, connected to, and/or engaged with the proximal portion of the frame, such as by adhesion, welding, mechanical fastening, and the like.

[0033] In some embodiments the core wire 30 may include a guide element 35 disposed adjacent a proximal end of the threaded member 36. In some embodiments, the guide element 35 may be configured and/or adapted to center the core wire 30 within the lumen 42 of the delivery catheter 40. In some embodiments, the guide element 35 may be slidably disposed about the core wire 30. In some embodiments, the guide element 35 may be positioned against the threaded member 36 and axially retained in place by a polymeric jacket 38 disposed over and/or on the core wire 30 and in contact with the guide element 35 at a distal end of the polymeric jacket 38. In some embodiments, the guide element 35 may be fixedly

and/or permanently attached to the core wire 30, such as by adhesion, welding, mechanical fastening, and the like. In some embodiments, the guide element 35 may be integrally formed with the core wire 30 as a monolithic unit. In some embodiments, a marker band 37 may be disposed about the core wire 30 adjacent the guide element 35. In some embodiments, the marker band 37 may be disposed over the polymeric jacket 38 and may crimp a distal portion of the polymeric jacket 38 covering the core wire 30 onto the core wire 30. In some embodiments, a discrete piece of polymeric material 39 may be disposed over the marker band 37, as seen for example in Figures 7-9. In some embodiments, the discrete piece of material 39 may be heated and/or joined to the polymeric jacket 38, such as by reflow, for example, to form a single polymeric cover member. In some embodiments, the marker band 37 may be at least partially encapsulated by the polymeric jacket 38, the discrete piece of polymeric material 39, and/or the polymeric cover member. In some embodiments, the discrete piece of polymeric material 39 may form the guide element 35, as seen for example in Figure 9.

[0034] In some embodiments, a core wire 30 may include a stepped outer diameter and/or a narrowed distal section adjacent a threaded member 36 disposed at the distal end 32, as may be seen in Figures 10-11. A polymeric jacket 38 disposed over and/or on the core wire 30 may be formed, crimped, or otherwise forced into place over the narrowed distal section, resulting in a portion of the polymeric jacket 38 being mechanically locked into place and preventing the polymeric jacket 38 from sliding proximally relative to the core wire 30. In some embodiments, the marker band 37 may mechanically lock the polymeric jacket 38 in place relative to the core wire 30. The mechanical locking may occur with or without the guide element 35 disposed adjacent the threaded member 36.

[0035] A method of making a centering core wire may include some or all of the steps of

obtaining or providing an elongate core wire 30 having a threaded member 36 disposed at a distal end 32 thereof;
obtaining or providing a guide element 35 having an aperture or lumen disposed therein;
inserting a proximal end 34 of the elongate core wire 30 into the aperture of lumen, such that a proximally-facing surface of the guide element 35 provides a generally tapered, angled, or convex surface in a radially outward and distal direction from the core wire 30;
sliding the guide element 35 distally over the elongate core wire 30 and into contact with a proximal end of the threaded member 36;
applying a polymeric jacket 38 over the elongate core wire 30 from the proximal end 34 of the elongate core wire 30 to the guide element 35, wherein the polymeric jacket 38 axially holds and/or retains the

guide element 35 against the threaded member 36; disposing a marker band 37 over the polymeric jacket 38 adjacent the guide element 35; crimping the marker band 37 onto the elongate core wire 30 such that the polymeric jacket 38 is fixed in position along the elongate core wire 30; disposing a piece of polymeric material 39 about the marker band 37; and heating the polymeric jacket 38 and the piece of polymeric material 39 such that the polymeric jacket 38 and the piece of polymeric material 39 are joined together by reflow to form a polymeric cover member.

[0036] In some embodiments of the method, the marker band 37 may be at least partially encapsulated by reflow of the polymeric jacket 38 and the piece of polymeric material 39. In other words, the marker band 37 may be at least partially encapsulated by the polymeric cover member formed by reflow of the polymeric jacket 38 and the piece of polymeric material 39. In some embodiments of the method, the elongate core wire 30 may include a stepped outer diameter and/or a narrowed section adjacent the threaded member 36 for providing a mechanical interlock between the core wire 30 and the polymeric jacket 38.

[0037] Figures 3 and 4 illustrate an example medical implant having a membrane or occlusive element disposed over at least a portion of the frame. In some embodiments, at least some of the plurality of proximally-facing hooks project through the membrane or occlusive element. In some embodiments, the membrane or occlusive element may be attached to the frame at each proximally-facing hook, for example, by passing each proximally-facing hook through the membrane or occlusive element, such as through a pore or aperture. In some embodiments, the membrane or occlusive element may be attached to the frame by other suitable attachment means, such as but not limited to, adhesive(s), sutures or thread(s), welding or soldering, or combinations thereof. In some embodiments, the membrane or occlusive element may be permeable or impermeable to blood and/or other fluids, such as water. In some embodiments, the membrane or occlusive element may include a polymeric membrane, a metallic or polymeric mesh, a porous filter-like material, or other suitable construction. In some embodiments, the membrane or occlusive element prevents thrombi (i.e. blood clots, etc.) from passing through the membrane or occlusive element and out of the left atrial appendage into the blood stream. In some embodiments, the membrane or occlusive element promotes endothelialization after implantation, thereby effectively removing the left atrial appendage from the patient's circulatory system.

[0038] The frame may be compliant and substantially conform to and/or be in sealing engagement with the shape and/or geometry of a lateral wall of a left atrial appendage in the expanded configuration. In some em-

bodiments, the medical implant may expand to a size, extent, or shape less than or different from a maximum unconstrained extent, as determined by the surrounding tissue and/or lateral wall of the left atrial appendage. Reducing the thickness of the plurality of struts may increase the flexibility and compliance of the support frame and/or the implant, thereby permitting the implant to conform to the tissue around it, rather than forcing the tissue to conform to the implant.

[0039] In some embodiments, the plurality of struts of the frame, the plurality of proximally-facing hooks, and/or the core wire may be formed of or include a metallic material, a metallic alloy, a ceramic material, a rigid or high performance polymer, a metallic-polymer composite, combinations thereof, and the like. Some examples of some suitable materials may include metallic materials and/or alloys such as stainless steel (e.g., 303, 304v, or 316L stainless steel), nickel-titanium alloy (e.g., nitinol, such as super elastic or linear elastic nitinol), nickel-chromium alloy, nickel-chromium-iron alloy, cobalt alloy, nickel, titanium, platinum, or alternatively, a polymer material, such as a high performance polymer, or other suitable materials, and the like. The word nitinol was coined by a group of researchers at the United States Naval Ordinance Laboratory (NOL) who were the first to observe the shape memory behavior of this material. The word nitinol is an acronym including the chemical symbol for nickel (Ni), the chemical symbol for titanium (Ti), and an acronym identifying the Naval Ordinance Laboratory (NOL).

[0040] In some embodiments, the plurality of struts of the frame, the plurality of proximally-facing hooks, and/or the marker band may be mixed with, may be doped with, may be coated with, or may otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique such as X-ray during a medical procedure. This relatively bright image aids the user of device in determining its location. Suitable radiopaque materials may include, but are not limited to, bismuth subcarbonate, iodine, gold, platinum, palladium, tantalum, tungsten or tungsten alloy, and the like.

[0041] In some embodiments, the membrane or occlusive element may be formed of or include a polymeric material, a metallic or metallic alloy material, a metallic-polymer composite, combinations thereof, and the like. In some embodiments, the membrane or occlusive element is preferably formed of polyethylene terephthalate (PET) such as DACRON®, or expanded polytetrafluoroethylene (ePTFE). Other examples of suitable polymers may include polyurethane, a polyether-ester such as ARNITEL® available from DSM Engineering Plastics, a polyester such as HYTREL® available from DuPont, a linear low density polyethylene such as REXELL®, a polyamide such as DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem, an elastomeric polyamide, a block polyamide/ether, a polyether block amide

such as PEBA available under the trade name PEBAX®, silicones, polyethylene, Marlex high-density polyethylene, polytetrafluoroethylene (PTFE), polyetheretherketone (PEEK), polyimide (PI), and polyetherimide (PEI), a liquid crystal polymer (LCP) alone or blended with other materials.

[0042] In some embodiments, the delivery catheter and/or the medical implant may be made from, may be mixed with, may be coated with, or may otherwise include a material that provides a smooth, slippery outer surface. In some embodiments, the delivery catheter and/or the medical implant may include or be coated with a lubricious coating, a hydrophilic coating, a hydrophobic coating, a drug-eluting material, an anti-thrombus coating, or other suitable coating depending on the intended use or application.

[0043] It should be understood that although the above discussion was focused on a medical device and methods of use within the vascular system of a patient, other medical devices or methods in accordance with the disclosure can be adapted and configured for use in other parts of the anatomy of a patient. For example, devices and methods in accordance with the disclosure can be adapted for use in the digestive or gastrointestinal tract, such as in the mouth, throat, small and large intestine, colon, rectum, and the like. For another example, devices and methods can be adapted and configured for use within the respiratory tract, such as in the mouth, nose, throat, bronchial passages, nasal passages, lungs, and the like. Similarly, the apparatus and/or medical devices described herein with respect to percutaneous deployment may be used in other types of surgical procedures as appropriate. For example, the medical devices may be deployed in a non-percutaneous procedure, such as an open heart procedure. Devices in accordance with the invention can also be adapted and configured for other uses within the anatomy.

[0044] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps. The scope of the invention is defined in the appended claims.

Claims

1. A medical implant (200), comprising:

a frame (210) configured to actuate between a collapsed configuration and an expanded configuration;
an occlusive element (220) covering at least a portion of the frame (210);
wherein a proximal end of the frame (210) forms a generally tubular portion (212), the tubular portion being configured to attach to a distal end (32) of a core wire (30);
wherein the tubular portion (212) of the frame

(210) includes a threaded insert (230) coupled thereto;

characterized in that the frame (210) includes an annular collar member (240) that is at least partially disposed within the tubular portion (212) and coupled thereto, the threaded insert (230) being coupled to the annular collar member (240); and

a pin element (250) coupling the annular collar member (240) to the frame (210).

2. The implant of claim 1, wherein the annular collar member (240) is disposed between the generally tubular portion (212) of the frame (210) and the threaded insert (230).

3. The implant of claim 1, wherein the threaded insert (230) is disposed within the annular collar member (240).

4. The implant of claim 3, wherein a portion of the occlusive element (220) is disposed between the threaded insert (230) and the annular collar member (240).

5. The implant of claim 1, wherein the frame (212) includes a plurality of proximally-facing hooks (218) disposed about a periphery of the frame (210) in the expanded configuration.

6. The implant of claim 4, wherein the threaded insert (230) is disposed distally of a portion of the occlusive element (220) disposed outside of the annular collar member (240).

7. The implant of claim 4, wherein an outer portion of the occlusive element (220) is defined as that part of the occlusive element (220) disposed outside of the annular collar member (240), wherein the outer portion of the occlusive element (220) is disposed radially outward from the threaded insert (230) in the expanded configuration.

8. The implant of claim 1, wherein the distal end (32) of the core wire (30) includes a threaded member (36) configured to mate with the threaded insert (230).

9. An occlusive implant system, comprising:

a catheter (40) having a lumen (42) extending therethrough;
a core wire (30) slidably and rotatably disposed within the lumen (42), the core wire (30) having a threaded member (36) disposed at a distal end thereof; and
the medical implant (200) of any one of claims 1 to 8, wherein the threaded member (36) is re-

movably coupled to the threaded insert (230).

10. The occlusive implant system of claim 9, wherein a portion of the occlusive element (220) is disposed between the threaded insert (230) and the proximal portion of the frame (210). 5
11. The occlusive implant system of claim 9, wherein a portion of the occlusive element (220) extends proximally of the threaded insert (230). 10
12. The occlusive implant system of claim 9, wherein the core wire (30) includes a guide element (35) disposed adjacent a proximal end of the threaded member (36), the guide element (35) being configured to center the core wire (30) within the catheter (40). 15
13. The occlusive implant system of claim 12, wherein the guide element (35) includes a proximal surface and a generally flat distal surface and a generally rounded convex outer surface, wherein the proximal surface of the guide element (35) is either conical or convex. 20
14. The occlusive implant system of claim 12, wherein the guide element (35) is either disposed or slidably disposed about the core wire (30) or is fixedly attached to the core wire (30). 25
15. The occlusive implant system of claim 12, further including a marker band (37) disposed about the core wire (30) adjacent the guide element (35), the marker band (37) crimping a distal portion of a polymeric jacket (38) covering the core wire (30) onto the core wire (30) and being at least partially encapsulated by a polymeric covering member, the polymeric covering member including the polymeric jacket (38). 30

Patentansprüche

1. Medizinisches Implantat (200), das aufweist:

einen Rahmen (210), der so konfiguriert ist, dass er zwischen einer kollabierten Konfiguration und einer expandierten Konfiguration betätigt wird; ein Okklusivelement (220), das mindestens einen Abschnitt des Rahmens (210) abdeckt; wobei ein proximales Ende des Rahmens (210) einen allgemein röhrenförmigen Abschnitt (212) bildet, wobei der röhrenförmige Abschnitt so konfiguriert ist, dass er an einem distalen Ende (32) eines Kerndrahts (30) angebracht wird; wobei der röhrenförmige Abschnitt (212) des Rahmens (210) einen damit gekoppelten Gewindeeinsatz (230) aufweist; **dadurch gekennzeichnet, dass**

der Rahmen (210) ein ringförmiges Bundteil (240) aufweist, das mindestens teilweise im röhrenförmigen Abschnitt (212) angeordnet und damit gekoppelt ist, wobei der Gewindeeinsatz (230) mit dem ringförmigen Bundteil (240) gekoppelt ist; und ein Stiftelement (250), das das ringförmige Bundteil (240) mit dem Rahmen (210) koppelt.

2. Implantat nach Anspruch 1, wobei das ringförmige Bundteil (240) zwischen dem allgemein röhrenförmigen Abschnitt (212) des Rahmens (210) und dem Gewindeeinsatz (230) angeordnet ist.
3. Implantat nach Anspruch 1, wobei der Gewindeeinsatz (230) im ringförmigen Bundteil (240) angeordnet ist.
4. Implantat nach Anspruch 3, wobei ein Abschnitt des Okklusivlements (220) zwischen dem Gewindeeinsatz (230) und dem ringförmigen Bundteil (240) angeordnet ist.
5. Implantat nach Anspruch 1, wobei der Rahmen (212) mehrere proximal weisende Haken (218) aufweist, die um einen Umfang des Rahmens (210) in der expandierten Konfiguration angeordnet sind.
6. Implantat nach Anspruch 4, wobei der Gewindeeinsatz (230) distal von einem Abschnitt des Okklusivlements (220) angeordnet ist, der außerhalb des ringförmigen Bundteils (240) angeordnet ist.
7. Implantat nach Anspruch 4, wobei ein Außenabschnitt des Okklusivlements (220) als der Teil des Okklusivlements (220) definiert ist, der außerhalb des ringförmigen Bundteils (240) angeordnet ist, wobei der Außenabschnitt des Okklusivlements (220) vom Gewindeeinsatz (230) in der expandierten Konfiguration radial nach außen angeordnet ist.
8. Implantat nach Anspruch 1, wobei das distale Ende (32) des Kerndrahts (30) ein Gewindeteil (36) aufweist, das so konfiguriert ist, dass es sich mit dem Gewindeeinsatz (230) paart.
9. Okklusivimplantat-System, das aufweist:

einen Katheter (40) mit einem sich durch ihn erstreckenden Lumen (42);

einen Kerndraht (30), der im Lumen (42) verschiebbar und drehbar angeordnet ist, wobei der Kerndraht (30) ein Gewindeteil (36) hat, das an einem distalen Ende davon angeordnet ist; und

das medizinische Implantat (200) nach einem der Ansprüche 1 bis 8, wobei das Gewindeteil (36) mit dem Gewindeeinsatz (230) entfernbar

gekoppelt ist.

10. Okklusivimplantat-System nach Anspruch 9, wobei ein Abschnitt des Okklusivelements (220) zwischen dem Gewindeeinsatz (230) und dem proximalen Abschnitt des Rahmens (210) angeordnet ist. 5
11. Okklusivimplantat-System nach Anspruch 9, wobei sich ein Abschnitt des Okklusivelements (220) proximal vom Gewindeeinsatz (230) erstreckt. 10
12. Okklusivimplantat-System nach Anspruch 9, wobei der Kerndraht (30) ein Führungselement (35) aufweist, das benachbart zu einem proximalen Ende des Gewindeteils (36) angeordnet ist, wobei das Führungselement (35) so konfiguriert ist, dass es den Kerndraht (30) im Katheter (40) zentriert. 15
13. Okklusivimplantat-System nach Anspruch 12, wobei das Führungselement (35) eine proximale Oberfläche und eine allgemein flache distale Oberfläche sowie eine allgemein abgerundete konvexe Außenfläche aufweist, wobei die proximale Oberfläche des Führungselements (35) konisch oder konvex ist. 20
14. Okklusivimplantat-System nach Anspruch 12, wobei das Führungselement (35) um den Kerndraht (30) angeordnet oder verschiebbar angeordnet ist oder am Kerndraht (30) fest angebracht ist. 25
15. Okklusivimplantat-System nach Anspruch 12, ferner mit einem Markerband (37), das um den Kerndraht (30) benachbart zum Führungselement (35) angeordnet ist, wobei das Markerband (37) einen distalen Abschnitt eines den Kerndraht (30) abdeckenden Polymermantels (38) auf den Kerndraht (30) presst und mindestens teilweise durch ein Polymerabdeckteil verkapselt ist, wobei das Polymerabdeckteil den Polymermantel (38) aufweist. 30

Revendications

1. Implant médical (200) comprenant : 45
 - un bâti (210) configuré pour fonctionner entre une configuration repliée et une configuration expansée ;
 - un élément occlusif (220) recouvrant au moins une partie du bâti (210) ; 50
 - dans lequel une extrémité proximale du bâti (210) forme une partie généralement tubulaire (212), la partie tubulaire étant configurée pour se fixer à une extrémité distale (32) d'une tige d'armature (30) ;
 - dans lequel la partie tubulaire (212) du bâti (210) comprend un insert fileté (230) couplé à cette dernière ; 55

caractérisé en ce que :

- le bâti (210) comprend un élément de collier annulaire (240) qui est au moins partiellement disposé dans la partie tubulaire (212) et couplé à cette dernière, l'insert fileté (230) étant couplé à l'élément de collier annulaire (240) ; et un élément de broche (250) couplant l'élément de collier annulaire (240) au bâti (210).
2. Implant selon la revendication 1, dans lequel l'élément de collier annulaire (240) est disposé entre la partie généralement tubulaire (212) du bâti (210) et l'insert fileté (230).
3. Implant selon la revendication 1, dans lequel l'insert fileté (230) est disposé dans l'élément de collier annulaire (240).
4. Implant selon la revendication 3, dans lequel une partie de l'élément occlusif (220) est disposée entre l'insert fileté (230) et l'élément de collier annulaire (240).
5. Implant selon la revendication 1, dans lequel le bâti (212) comprend une pluralité de crochets (218) orientés de manière proximale, disposés autour d'une périphérie du bâti (210) dans la configuration expansée.
6. Implant selon la revendication 4, dans lequel l'insert fileté (230) est disposé, de manière distale, par rapport à une partie de l'élément occlusif (220) disposée à l'extérieur de l'élément de collier annulaire (240).
7. Implant selon la revendication 4, dans lequel une partie externe de l'élément occlusif (220) est définie comme étant cette partie de l'élément occlusif (220) disposée à l'extérieur de l'élément de collier annulaire (240), dans lequel la partie externe de l'élément occlusif (220) est disposée radialement vers l'extérieur par rapport à l'insert fileté (230) dans la configuration expansée.
8. Implant selon la revendication 1, dans lequel l'extrémité distale (32) de la tige d'armature (30) comprend un élément fileté (36) configuré pour se coupler avec l'insert fileté (230).
9. Système d'implant occlusif comprenant :
 - un cathéter (40) ayant une lumière (42) s'étendant à travers ce dernier ;
 - une tige d'armature (30) disposée de manière coulissante et rotative à l'intérieur de la lumière (42), la tige d'armature (30) ayant un élément fileté (36) disposé au niveau de son extrémité

distale ; et
l'implant médical (200) selon l'une quelconque
des revendications 1 à 8, dans lequel l'élément
fileté (36) est couplé, de manière amovible, à
l'insert fileté (230).

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10. Système d'implant occlusif selon la revendication 9,
dans lequel une partie de l'élément occlusif (220) est
disposée entre l'insert fileté (230) et la partie proxi-
male du bâti (210). 10
11. Système d'implant occlusif selon la revendication 9,
dans lequel une partie de l'élément occlusif (220)
s'étend de manière proximale par rapport à l'insert
fileté (230). 15
12. Système d'implant occlusif selon la revendication 9,
dans lequel la tige d'armature (30) comprend un élé-
ment de guidage (35) disposé de manière adjacente
à une extrémité proximale de l'élément fileté (36), 20
l'élément de guidage (35) étant configuré pour cen-
trer la tige d'armature (30) dans le cathéter (40).
13. Système d'implant occlusif selon la revendication
12, dans lequel l'élément de guidage (35) comprend 25
une surface proximale et une surface distale géné-
ralement plate et une surface externe convexe gé-
néralement arrondie, dans lequel la surface proxi-
male de l'élément de guidage (35) est conique ou
convexe. 30
14. Système d'implant occlusif selon la revendication
12, dans lequel l'élément de guidage (35) est dispo-
sé ou disposé de manière coulissante autour de la
tige d'armature (30) ou est fixé de manière fixe à la 35
tige d'armature (30).
15. Système d'implant occlusif selon la revendication
12, comprenant en outre une bande de marqueur
(37) disposée autour de la tige d'armature (30) ad- 40
jacente à l'élément de guidage (35), la bande de mar-
queur (37) sertissant une partie distale d'une chemi-
se polymère (38) recouvrant la tige d'armature (30)
sur la tige d'armature (30) et étant au moins partiel- 45
lement encapsulée par un élément de revêtement
polymère, l'élément de revêtement polymère com-
prenant la chemise polymère (38).

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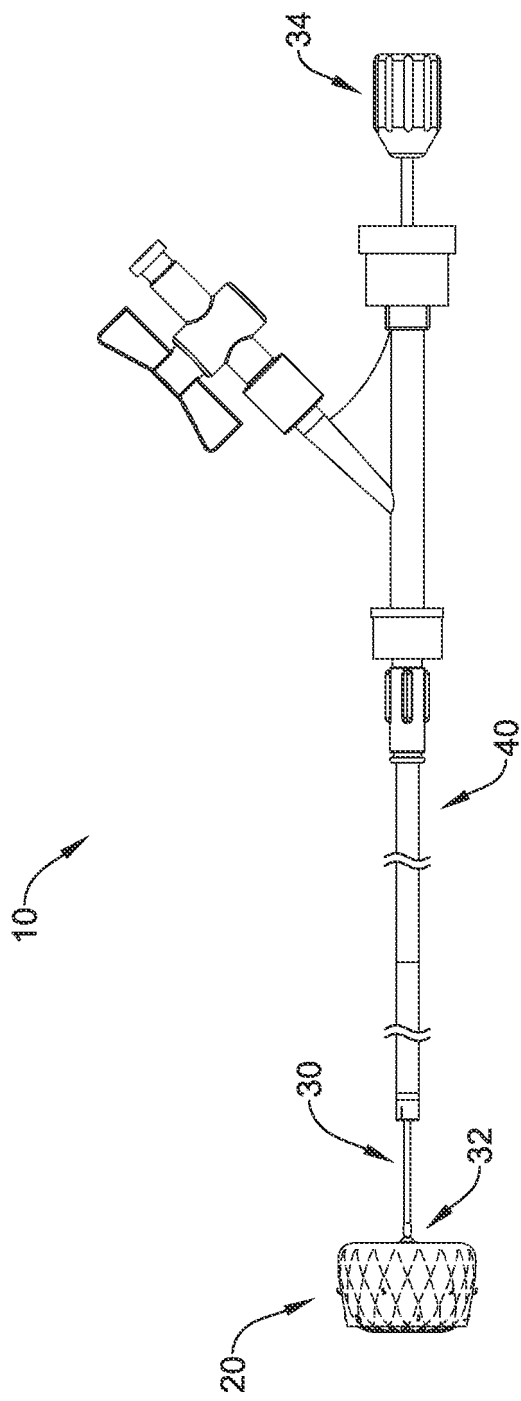


FIG. 1

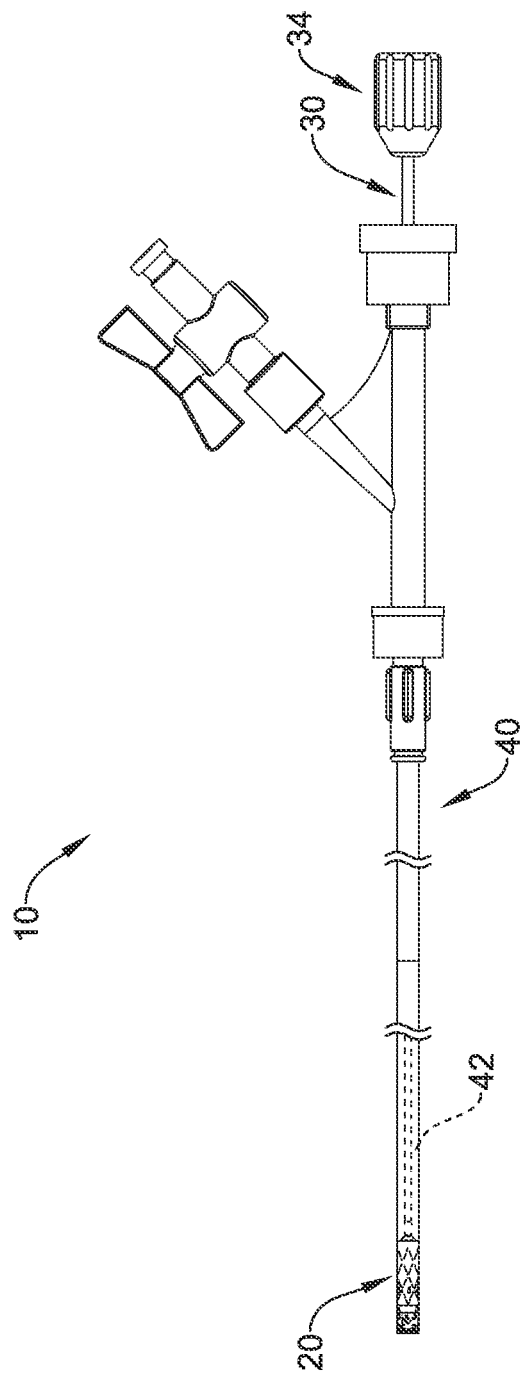


FIG. 2

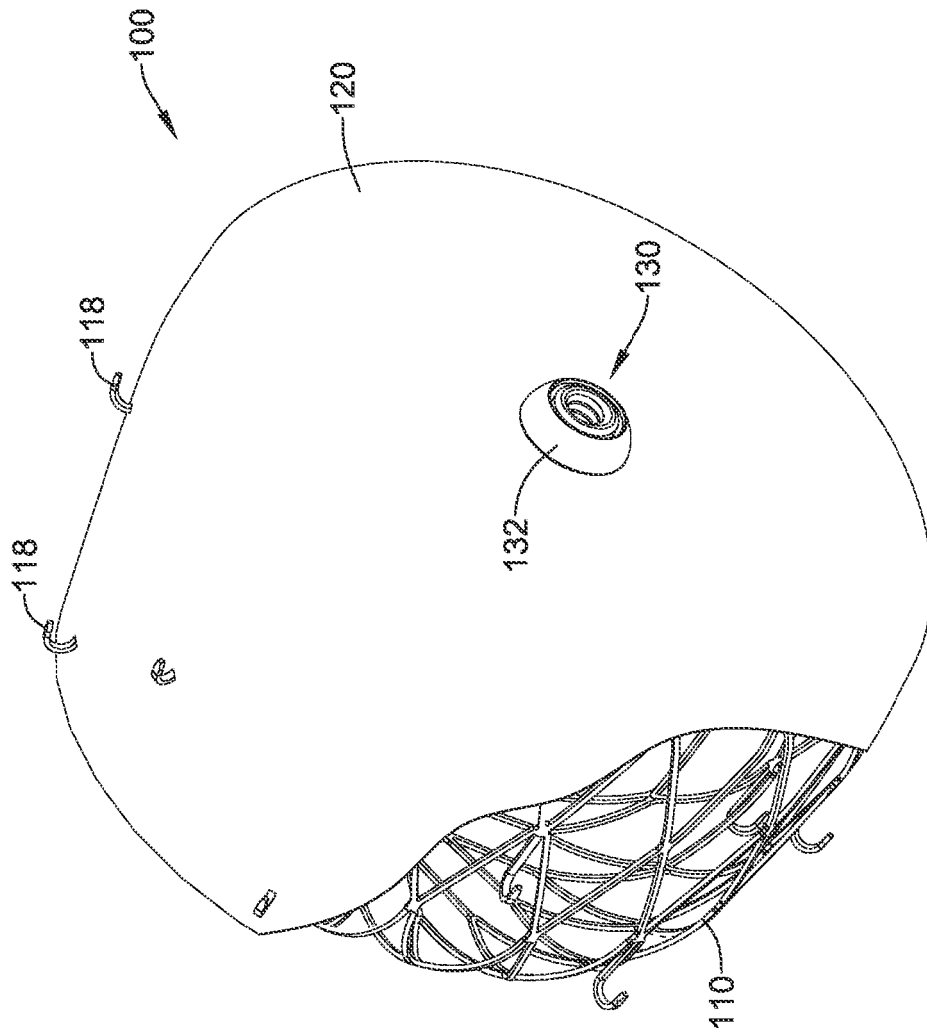


FIG. 3

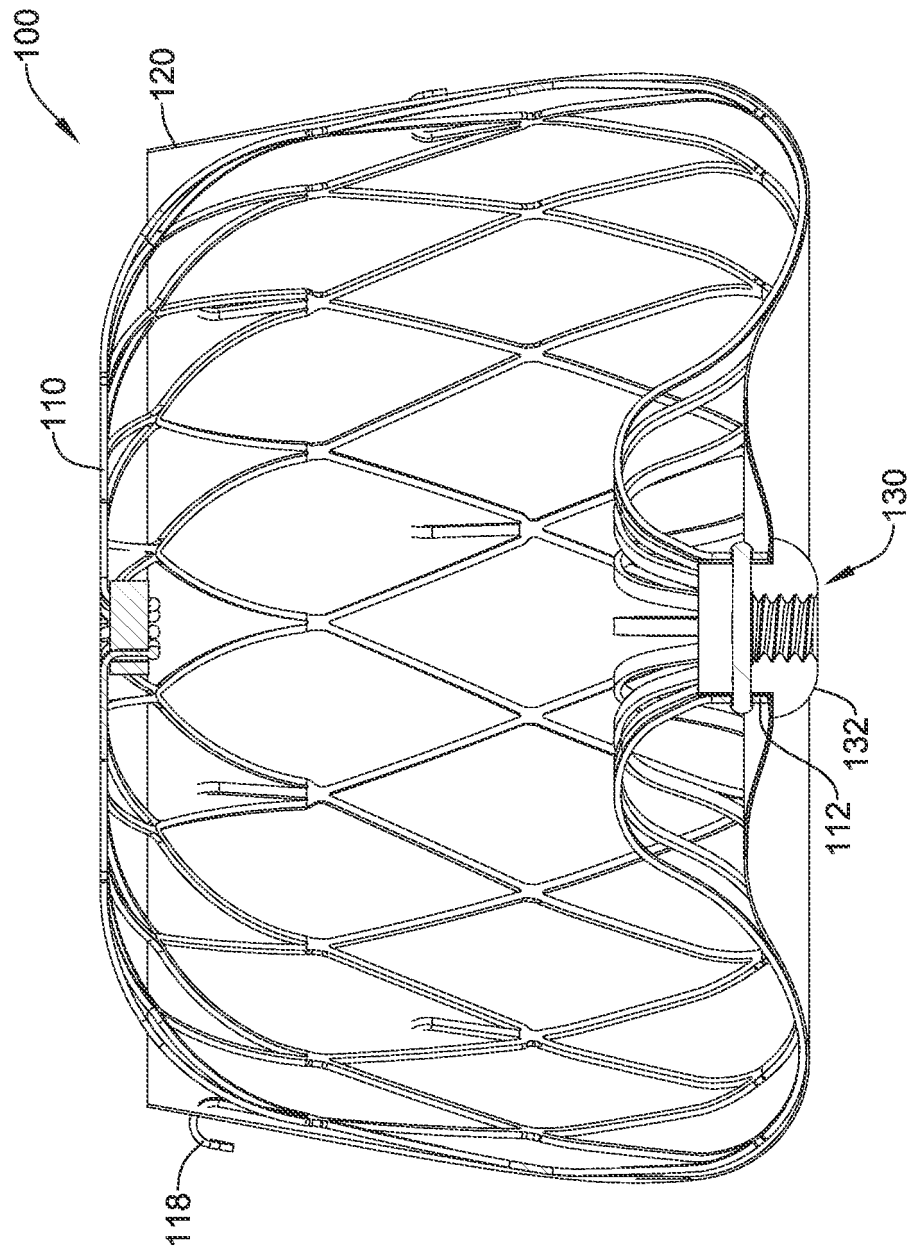


FIG. 3A

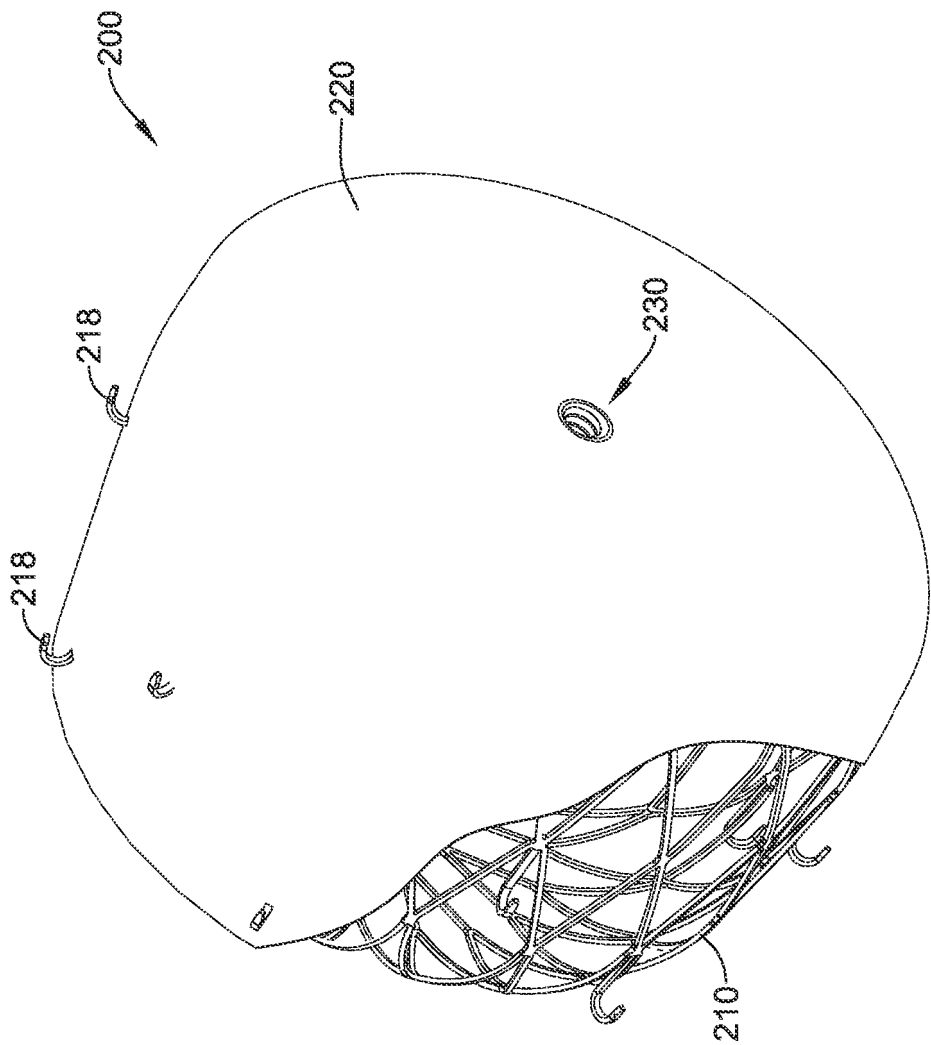


FIG. 4

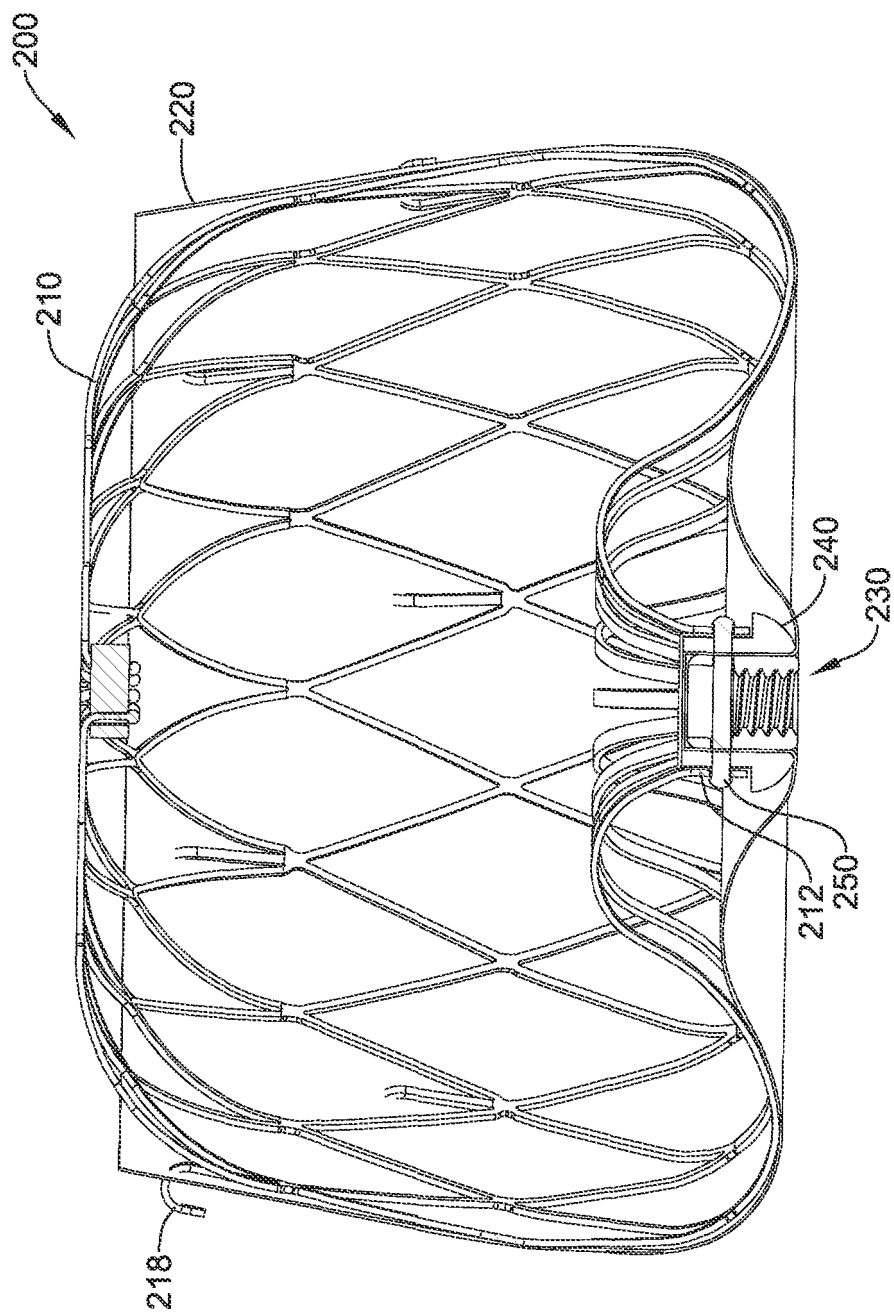
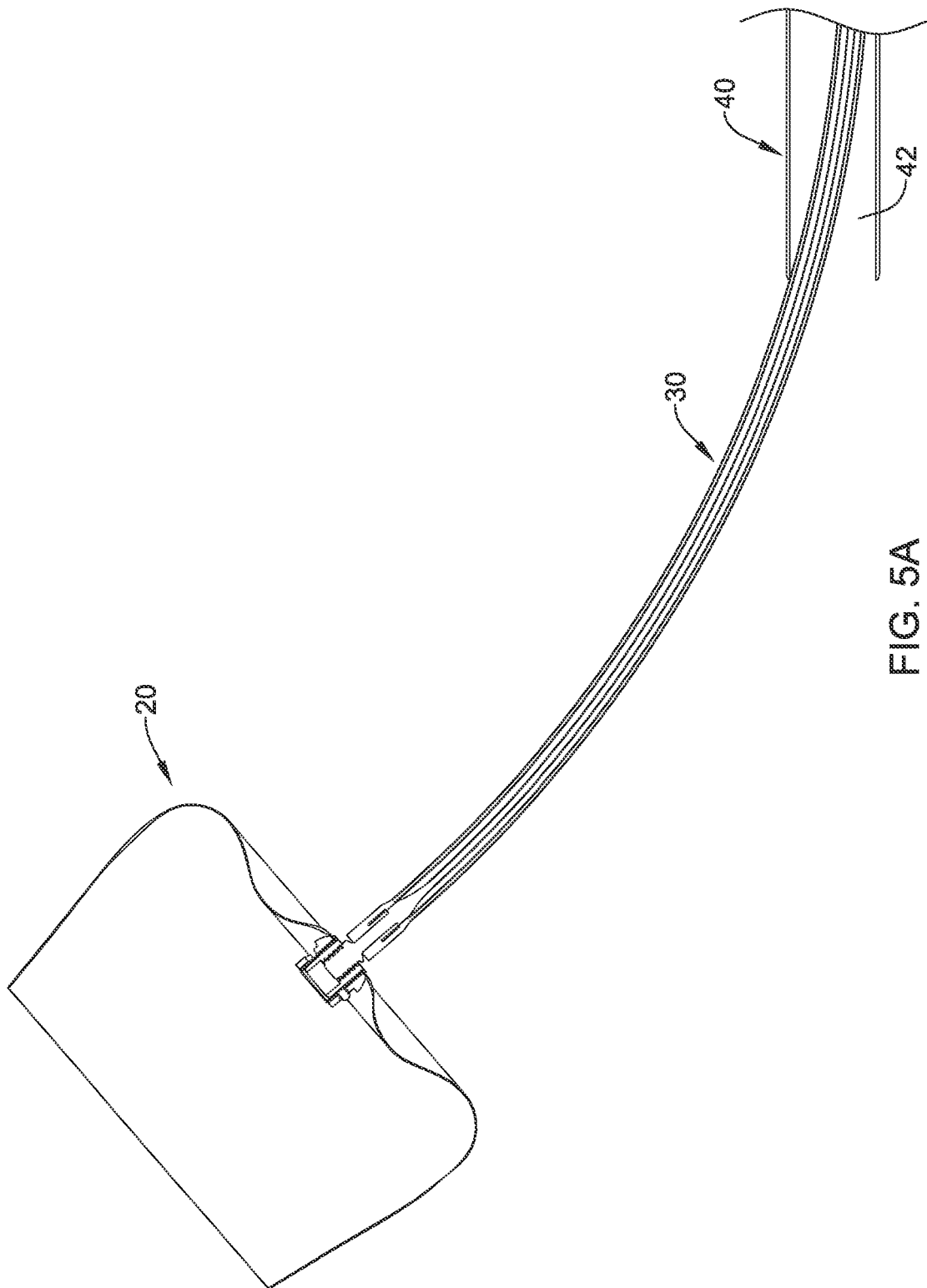


FIG. 4A



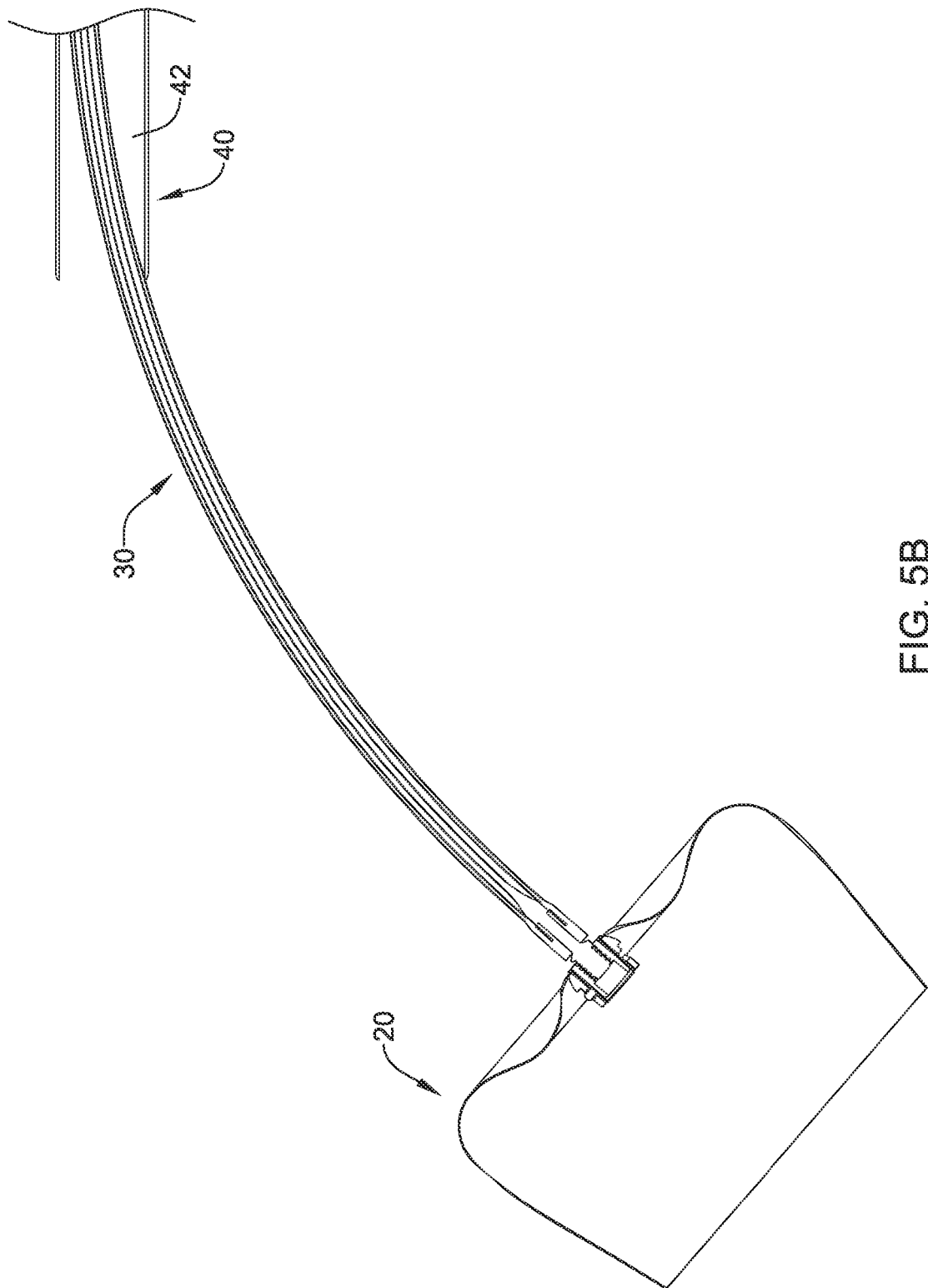


FIG. 5B

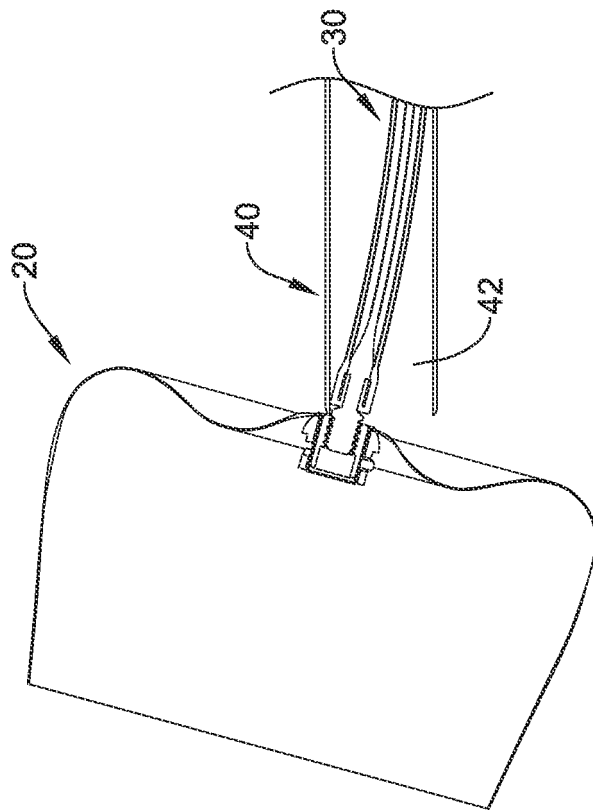


FIG. 6

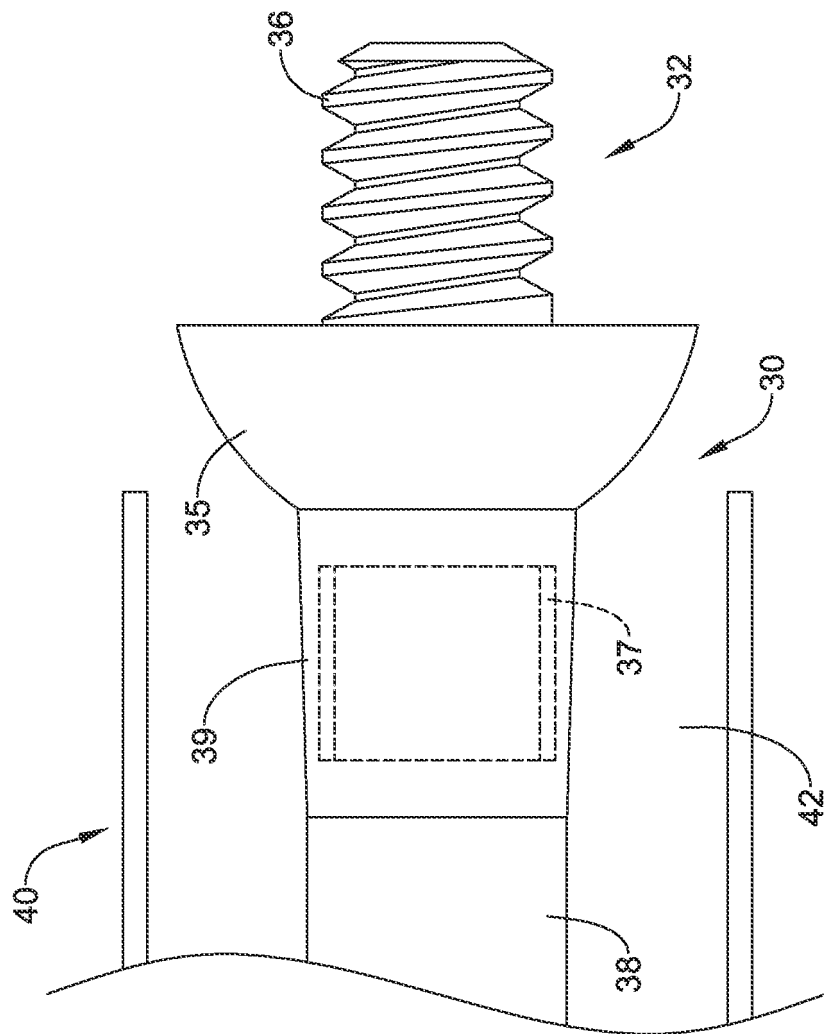


FIG. 7

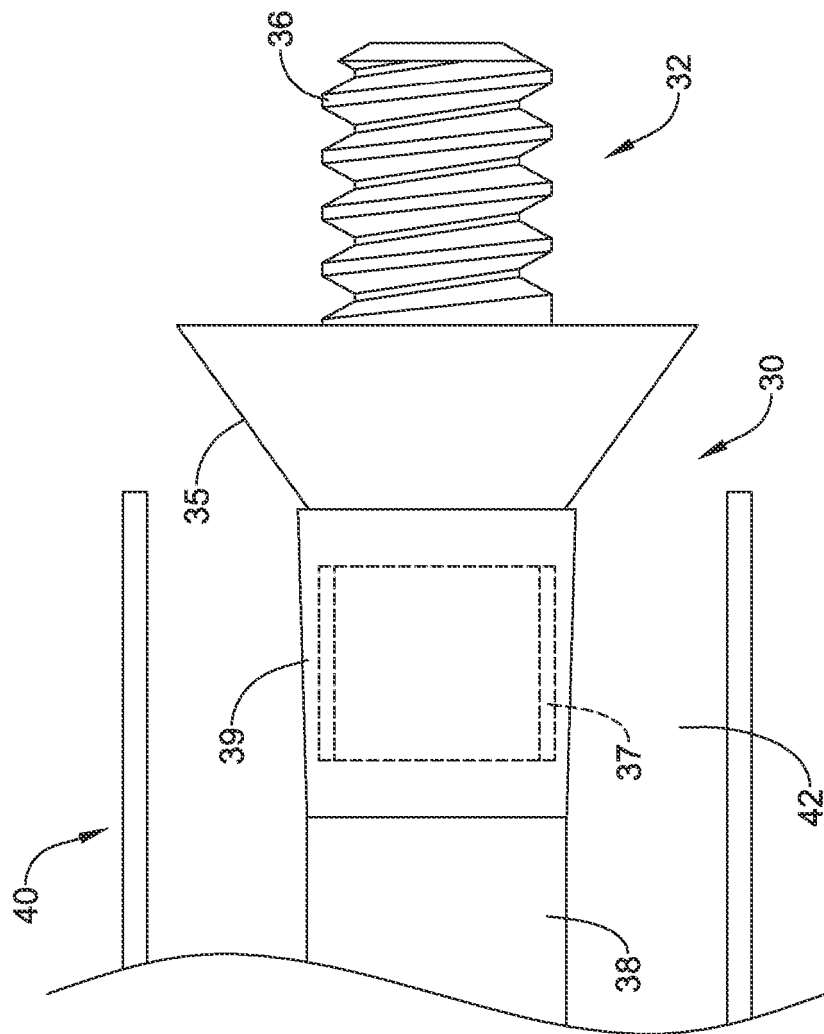


FIG. 8

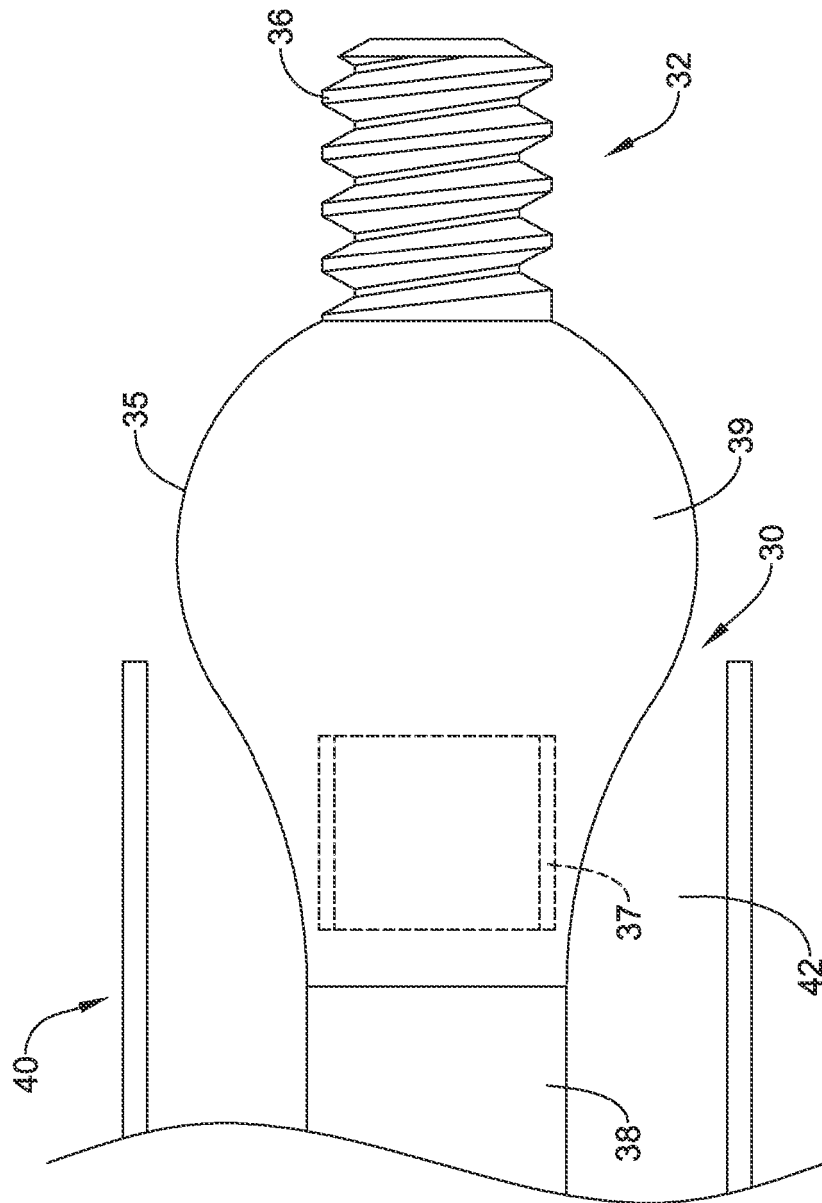


FIG. 9

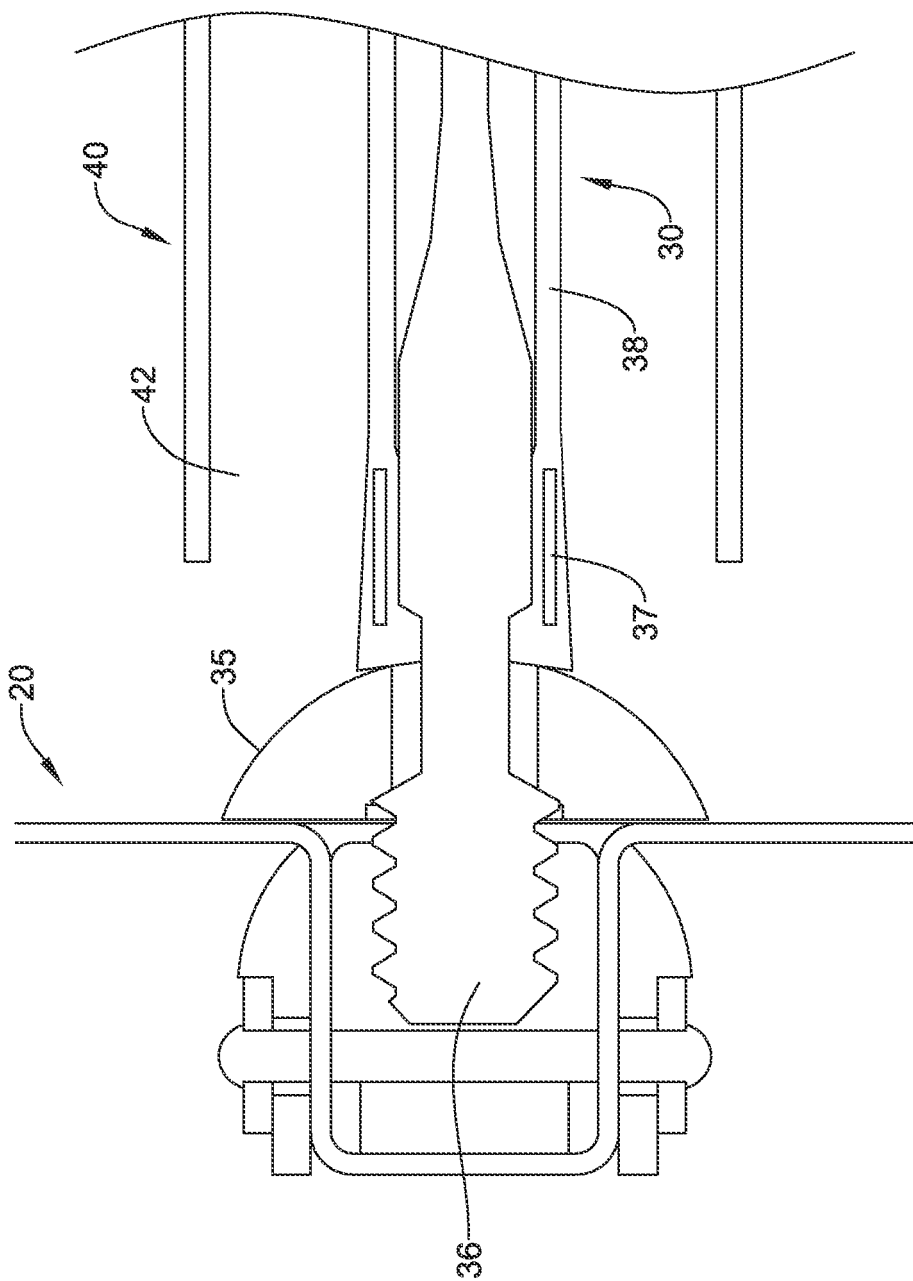


FIG. 10

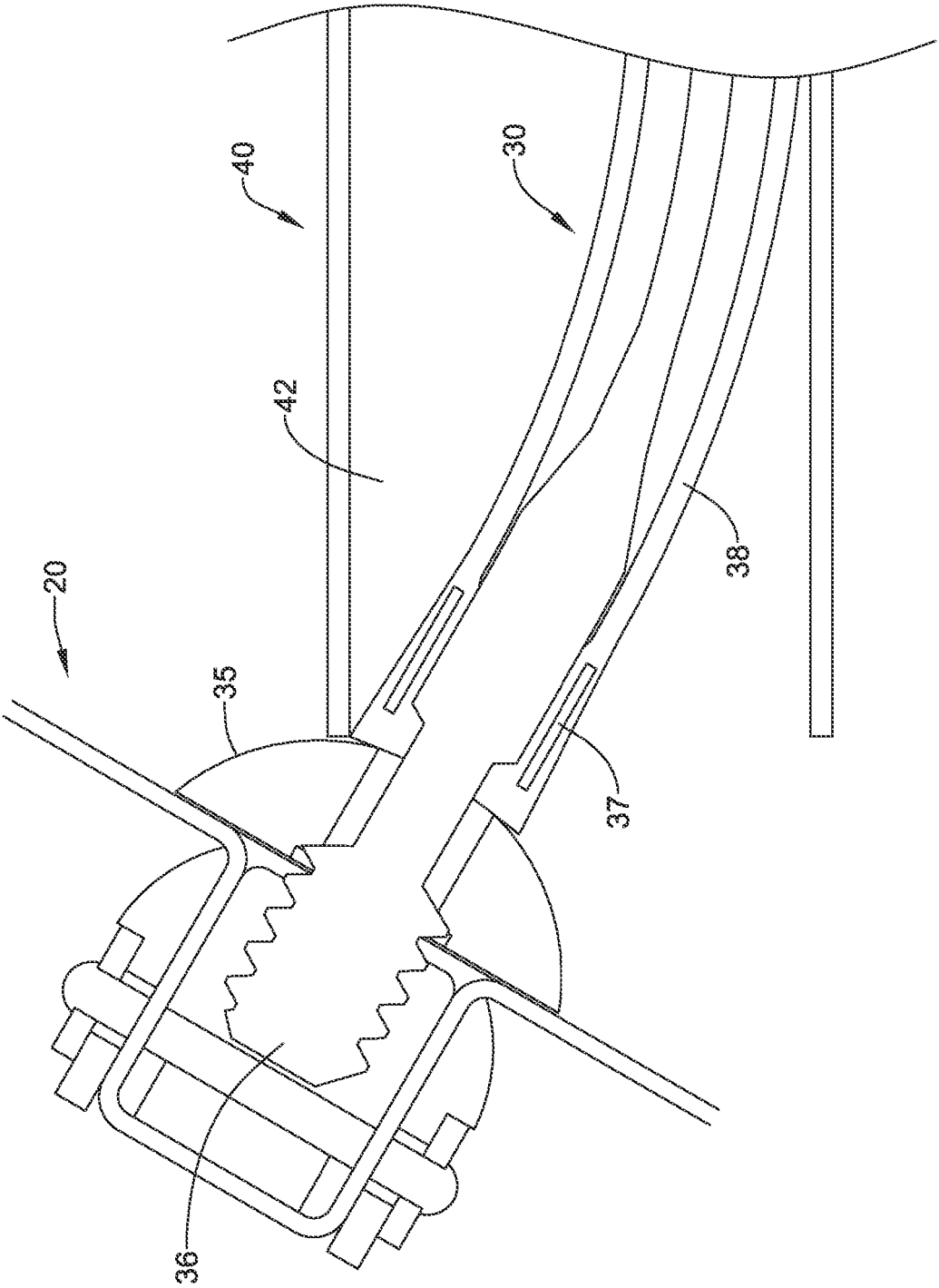


FIG. 10A

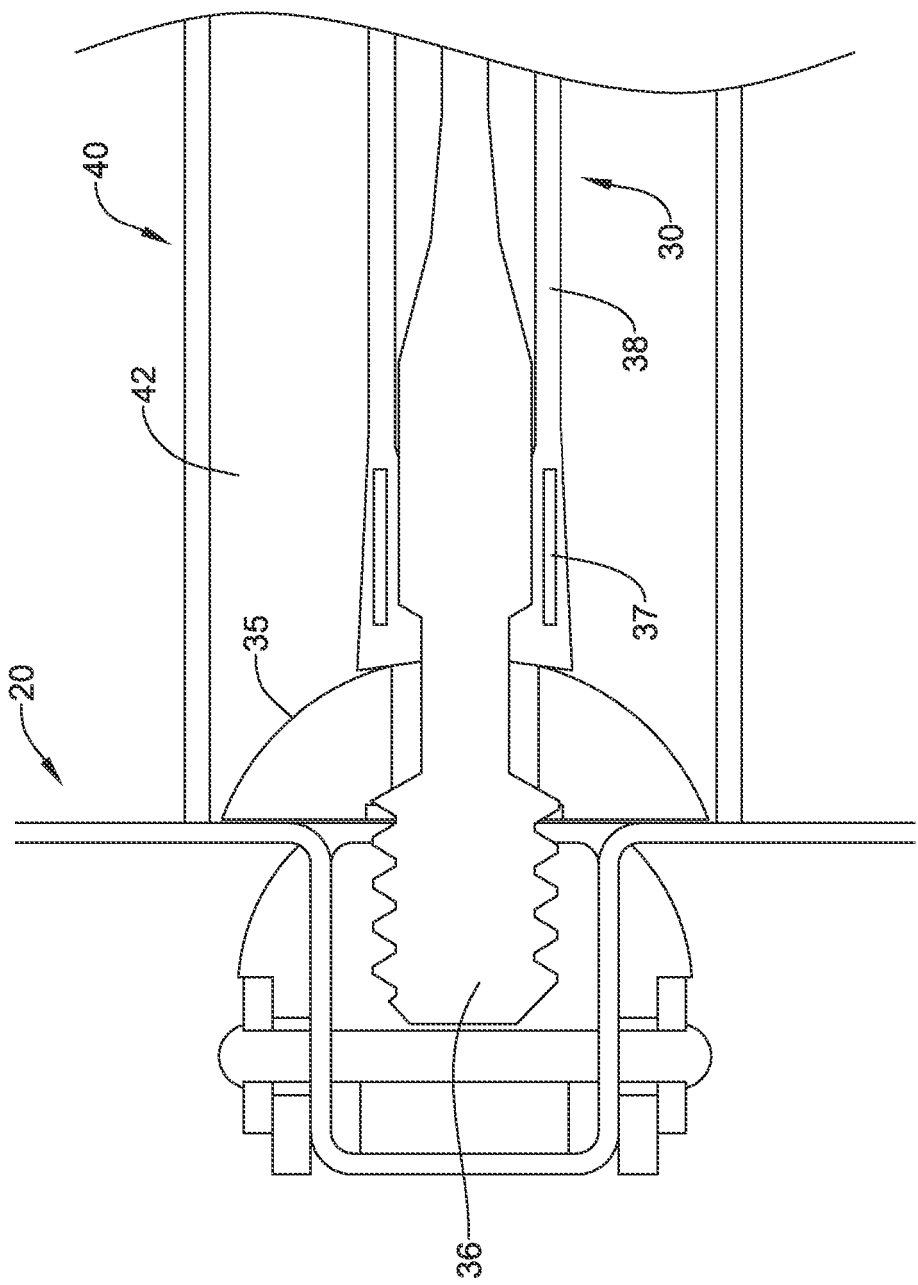


FIG. 11

REFERENCES CITED IN THE DESCRIPTION

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